

EFFICACY OF INJECTABLE NOR-ETHISTERONE ENANTHATE IN FERTILITY CONTROL

by

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Introduction

Following the popularity of progesterone as family planning therapy in the West, work is now in progress to overcome a great objection of tedious routine of taking pills daily which has been the greatest objection to its acceptance by masses in our country. It was thought that the ideal alternative would be an injectable contraceptive which provided a long interval of continuous protection. Only one injection provides freedom from the strict regimen of oral contraceptive for 90 days.

Materials and Methods

A total number of 50 cases were studied and were followed up for 290 months in one and a half year time. The cases were

selected from the patients attending the Family Planning Centre, Labour Room and the Outpatients' Department of Hospital for Women (Deptt. of Obstet. & Gynaecology), Patna Medical College Hospital, Patna. Such patients who were known to have high fertility, were chosen for study.

After proper history and clinical examinations deep intramuscular injection of 200 mg. of Norethisterone enanthate (SH 393) was given at the interval of every 3 months. Injections were given preferably between five to eight days of last menstruation.

After the injection the return appointment was scheduled 1 month after injection. Subsequent return visits were also scheduled at monthly interval.

TABLE I
Clinical Effectiveness of the Drug in a Total of 290 Months

No. of Cases	Pregnancy		Total month	% of failure
	Drug failure	Human failure		
3	1	2	290	0.25/100 Women/year
	Pregnancy in 3rd month after the last injection			

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Observations and Results

The majority of the cases were in the age group of 23 to 31 years which comprises 84% of the total number of cases. Majority were between para 2 to 6 which comprises 90 per cent of the total cases.

Table I shows the effectiveness of the

drug in total of 290 months in fifty patients in one and half year. One conception occurred during the 3rd months after the last injection.

Fifteen women did not appear for the second dose at the proper date, 2 amongst them became pregnant. One patient received injection after three and a half months and another after 4 months interval.

It is evident from Table II that the

TABLE II
Reestablishment of Fertility in Months Among 6 of the Patients After the Discontinuation of Therapy

Re-establishment of fertility in month	No. of cases
Second	0
Third	0
Fourth	2
Fifth	1
Sixth	0
Seventh	2
Eighth	1

patients returned to normal reproductive function spontaneously within 8 months of discontinuation of the therapy.

It is clearly evident from Table III that all of them had minor complaints only.

Table IV shows that the menstrual cycles remained unchanged in a smaller group of women which comprised only 8 per cent of all the cases while 50 per cent of them developed shorter or longer cycle.

TABLE IV
Effect on the Menstrual Cycles of 50 Women in a Total of 290 Months

Menstrual Cycle	No. of cases	Percentage
Normal	4	8
Longer (36 days)	10	20
Shorter (26 days)	15	30
Highly irregular	14	28
Amenorrhoea	4	8
Lactational	3	6

TABLE V
Effect on the Uterine Bleeding of 50 Cases in a Total of 290 Months

Uterine bleeding	No. of cases	Percentage
Normal	9	18
Decreased	15	30
Increased	11	22
Highly irregular	13	26
Spotting only	2	4

TABLE III
Side-effects

Side effects	First Cycle	Percentage	Total cycles	Percentage
Dysmenorrhoea	4	8	16	5.52
Headache	4	8	22	7.6
Dizziness	3	6	13	4.98
Nervousness	4	8	16	5.52
Cramps and pain in legs	2	4	16	5.52
Nausea	5	10	12	4.13
Vague pain in abdomen	1	2	4	1.33
Pain in chest	2	4	8	2.66
Allergic rashes	1	2	4	1.33
Leucorrhoea	3	6	6	2.05
Breast tenderness and lump	1	2	1	0.34

Thirty per cent of the women had scanty, 26 per cent irregular and 22 per cent profuse uterine bleeding, but 4 per cent of them showed a spotting after the injection.

Discussion

Majority of our cases were young and fertile and were in between para 2 to 6. In the present series 200 mg., intramuscular injection of nor-ethisterone enanthate was administered in 50 patients in total of 290 months in one and a half years time. Only 1 conception occurred during the third month of the last injection. This was considered to be a failure of therapy. Two conceptions occurred in the beginning of the 4th month of the last injection. In these 2 cases the patients were administered the injection after 10 days of their schedule cycle. Although 15 of the cases reported late for 10-25 days for the therapy, only 2 of them conceived. Thus we see that the therapy failure was only 0.5 per cent/100 women/year but if human factor is taken into account it comes upto 0.25 per cent/100 women/year as shown in Table I. Out of 50 patients, 6 became pregnant within 4-8 months of last injection after discontinuation of the therapy. Ten underwent sterilization, while 5 did not report after 3-6 months of last injection. The remaining 29 were satisfied with the therapy. Eleven women continued the therapy for 9-10 months with a very satisfactory outcome. During their trial Zanartu and Navaro (1968) found a 2.5 per cent of therapy failure with Norethisterone Enanthate. Chinnatamby (1971) reported pregnancy 2 to 3 per cent/100 women/year with SH 393.

Karim *et al* (1971) found that Norethisterone Enanthate (200 mg.) intramuscular every 84 days and Depot Pro-

vera 150 mg. intramuscular every 90 days were 100 per cent effective for contraceptive purposes.

The present series shows that the fertility was established soon after the discontinuation of the therapy. In this series, 6 patients conceived during the period of 1½ years (Table II) in which 2 patients became pregnant due to the late administration of the drug for 10 days. Of these 2, 1 had full term normal delivery at our hospital. There was no evidence of malformations in the child. The second had suction termination of pregnancy at Patna Medical College Hospital when she was 10 weeks pregnant. Zanartu and Navaro (1968) observed that fertility was established soon after the last injection.

Headache, giddiness were the most common side effects among the women under SH 393 which gradually diminished as the course of therapy increased.

In a total of 290 months in 1½ years time of only a small group of 50 women had normal cycle length after the therapy which comprised only 8% of the total cases. Zanartu and Navaro (1968) observed in their series that of 130 fertile women treated with SH 393 in a total of 2300 months, the cycle length was found to be regular in 10 per cent only.

Only 18 per cent of our patients had normal amount of bleeding after the therapy. It was scanty in 30 per cent, increased in 22 per cent, irregular in 26 per cent of the patients and spotting in 4 per cent.

Karim and Mahgoub (1971) reported in their series that the duration of the flow had a tendency to increase in the first, third and fifth cycles in patients who were treated by the cyclical injection of nor-ethisterone enanthate.

Indeed irregular cycles and heavy bleeding were the most frustrating side

effects of the therapy and was the most important cause for drop outs.

Extensive trial of the drug can only finally establish its practical usefulness for our mass Family Planning Programme.

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